K014247

JUN 0 3 2002

510(k) Summary

Triage® Drugs of Abuse Panel plus PPX

This 510(k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number: (To be determined)

A. Name and Address of Submitter

Company Name:	Biosite Incorporated
Address:	11030 Roselle Street San Diego, CA 92121
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Contact Person:	Jeffrey R. Dahlen, Ph.D.
Date Summary Prepared:	3/5/02

B. Device Names

1. Trade Name

   Triage® Drugs of Abuse Panel plus PPX

2. Common / Usual Name

   Test System for Drugs of Abuse

3. Classification Name

   Amphetamine test system

   Barbiturate test system

   Benzodiazepine test system

   Cocaine and cocaine metabolite test system

   Opiate test system

   Cannabinoid test system

   Tricyclic antidepressant drugs test system

   Propoxyphene test system

Phencyclidine test system (Note: the phencyclidine test system has not been classified but has the same intended use to measure phencyclidine in serum or urine.

C. Predicate Devices

Triage® Drugs of Abuse Panel plus TCA (Biosite Incorporated), and the TDX/TDXFLX Propoxyphene test (Abbott Laboratories).

D. Device Description and Intended Use

The Triage® Drugs of Abuse Panel Plus PPX is a competitive immunoassay used for the qualitative determination of the presence of the major metabolites of amphetamines, barbiturates, benzodiazepines, cocaine, opiates, phencyclidine, THC, tricyclic antidepressants, and propoxyphene in urine.

E. Summary of Performance Data

Interfering Substances: Substances that are commonly in human urine were tested for interference with results in samples spiked with drug 20% above the threshold concentration and samples spiked with drug 20% below the threshold concentration. None of the substances tested caused interference with the assay results.

Specificity/Cross-reactivity: Drugs and related substances were added to drug-free urine and tested using the Triage® Drugs of Abuse Panel plus PPX to determine the concentration that produces a positive result. The results are described in the labeling.

Imprecision: Imprecision was determined by measuring three contrived specimens with drug added at approximately 25% below the threshold concentration, the threshold concentration, and 25% above the threshold concentration. Three individuals evaluated each specimen ten times each day for three days. The precision results were consistent with the threshold validation results.

Threshold: Previously established thresholds (amphetamines 1000, methamphetamines 1000, barbiturates 300, benzodiazepines 300, tricyclic antidepressants 1000, phencyclidine 25, opiates 300, cocaine 300, and THC 50) were challenged by testing specimens containing each drug or drug metabolite spiked into drug-free urine at concentrations in increments of 25% above and 25% below the threshold. Each specimen was tested using the

Triage® Drugs of Abuse Panel plus PPX. The data indicated that the device is able to detect drug concentrations near the threshold and that the thresholds are set appropriately.

F. Conclusion

The results of performance studies demonstrate that the Triage® Drugs of Abuse Panel plus PPX is substantially equivalent to currently marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Jeffrey R. Dahlen, Ph.D.
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Clinical & Regulatory Affairs
Biosite Diagnostics
11030 Roselle Street
San Diego, CA 92121

JUN 0 3 2002

Re: k014247
Trade/Device Name: Triage® Drugs of Abuse Panel plus PPX
Regulation Number: 21 CFR 862.3100; 21 CFR 862.3150; 21 CFR 862.3170; 21 CFR 862.3870; 21 CFR 862.3250; 21 CFR 862.3650; 21 CFR 862.3700; 21 CFR 862.3910
Regulation Name: Amphetamine test system; Barbiturate test system; Benzodiazepine test system; Cannabinoid test system; Cocaine and cocaine metabolite test system; Opiate test system; Propoxyphene test system; Tricyclic antidepressant drugs test system
Regulatory Class: Class II
Product Code: DKZ; DIS; JXM; LDJ; DIO; DJG; LCM; JXN; LFG
Dated: May 21, 2002
Received: May 22, 2002

Dear Dr. Dahlen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): (to be determined)

Device Name: Triage® Drugs of Abuse Panel Plus PPX

Indications For Use:

The Triage® Drugs of Abuse Panel Plus PPX is a competitive immunoassay used for the qualitative determination of the presence of the major metabolites of amphetamines, barbiturates, benzodiazepines, cocaine, opiates, phencyclidine, THC, tricyclic antidepressants, and propoxyphene in urine.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K014247

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The Counter Use___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)